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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,631	08/25/2003	Tony Hunter	066671-0044	5328

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,631	HUNTER ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-5,8,9 and 19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21,28,33 and 34* is/are allowed.

6)☒ Claim(s) *4,5,8,9,19,20,22-27,29-32,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/25/05*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on 9/29/05 in response to the previous Non-Final Office Action (5/17/05) is acknowledged and has been entered.

Claims 1-3, 6-7, and 10-18 have been cancelled. Claims 4-5 and 8-9 have been amended. Claims 19-36 have been added. Claims 4-5, 8-9, and 19-36 are pending and under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

The following office action contains NEW GROUNDS of rejection.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 9/29/05 are/is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

Rejections/Objections Withdrawn

1. Specification

The objection of specification lacking cross-reference information to parent application is withdrawn in view of the Applicants amendment.

2. Priority

The objections of Applicant's claims to an earlier effective filing date through an US application 0855912 ('912), filed on 11/13/1995 and through US application 09/275900 ('900), filed on 03/24/1999, are withdrawn in view of the Applicants arguments. Therefore, The instant application has the priority to an earlier effective filing date through an US application 0855912, filed on 11/13/1995.

3. 35 U.S.C. 112, 2nd paragraph

The rejection of Claims 4, 8, 13 and 16 under 35 U.S:C. 112, second paragraph, as being indefinite of "**substantially the same**" is withdrawn in view of the amendment to claims.

The rejection of Claims 4, 7-8, and 11 under 35 U.S.C. 112, second paragraph, as being indefinite of ""**functional fragment**" is withdrawn in view of the amendment, cancellation to claims or Applicants argument.

4. 35 *U.S.C. 112, 1st paragraph*

a. The rejection of Claims 4-18 under 35 U.S.C. 112 first paragraph as new matter is withdrawn in view of applicants arguments.

b. The rejection of Claims 4, 6-8, 10-14, 16-17 under 35 U.S.C. 112 first paragraph as failing to comply with the written description requirement of terms "functional fragment", "sequence substantially the same", or "conservative variation" is withdrawn in view of Applicants' s arguments and amendments to the claims.

5. 35 *U.S.C. 102 (b)*

a. The rejection of Claims 4-18 under U.S.C. 102(b) as being anticipated by Hunter et al., (US Patent 5952467) or Lu et al., (Nature, vol 280, page 544-7, 1996) is withdrawn in view of withdrawal of objection of priority through an US application 0855912 ('912), filed on 11/13/1995 and US application 09/275900 ('900), filed on 03/24/1999.

b. The rejection of Claims 4-7 under U.S.C. 102(b) as being anticipated by Lu et al., (WO00/48621, 2000) is withdrawn in view of withdrawal of objection of priority through an US application 0855912 ('912), filed on 11/13/1995 and US application 09/275900 ('900), filed on 03/24/1999.

c. The rejection of Claims 8-11 under U.S.C. 102(b) as being anticipated by Fujimori,et al., (Biochem Biophys Res Commun, Vol 265, page 658-663, 1999) is withdrawn in view of withdrawal of objection of priority through an US application 0855912 ('912), filed on 11/13/1995 and US application 09/275900 ('900), filed on 03/24/1999. A

d. The rejection of Claims 12-15 under U.S.C. 102(b) as being anticipated by Tang et al., (WO01/79449) is withdrawn in view of cancellation of the claims.

e. The rejection of Claims 16-18 under U.S.C. 102(b) as being anticipated by Drmanac et al., (WO/0175067) is withdrawn in view of cancellation of the claims.

Response to Arguments

Rejection under *Double Patenting*

The rejection of Claims 4- 5 and 8-9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5952467 is maintained for the reasons of record in the prior Office Action (5/17/05, page 11) and made again for amended claims 4-5 and 8-9. Newly added claims 19-32 are also rejected with same reason. Applicants request deferral of this ground for rejection of until such time as allowable subject matter is indicated in the present application. Therefore, this rejection is maintained until that time.

The following is a New Ground of rejection

As drawn to new matter

Claims 22-25 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the claims 22-25 and 30-32 as newly added claims recite polypeptide comprising WW or PPIase domain of Pin1 consisting essentially of amino acid residues 5-43, or 59-163 of SEQID NO: 2, fused to a heterologous polypeptide, wherein the heterologous polypeptide is an epitope tag, a carrier protein, a DNA binding domain, a transactivation domain, or an enzyme suitable for use as a label. Instant specification as filed, although providing WW domain consisting of amino acid residues 5-43, PPIase domains consisting of an amino acid residues 59-163 of SEQID NO: 2, does not provide sufficient support for the instant claims reciting the WW and PPIase domains of Pin1 (SEQ ID NO: 2) fused to any heterologous polypeptide, or fused to a heterologous peptide consisting of an epitope tag, a carrier protein, a DNA binding domain, a transactivation domain, or an enzyme suitable for use as a label.

As drawn to Written Description

Claim 4-5, 8-9, 19-20, 22-27, 30, 35-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Claims 4-5, 8-9, 19-20, 22-27, 29-32 and 35-36 recite "Pin1 polypeptide **comprising"** or Pin 1 polypeptide **consisting essentially of** ", which read on adding any polypeptide with any amino acid sequence or any length polypeptide to the amino acid resided 5-43 and 59-163 of SEQ ID NO: 2 (Pin1) at any site, which maintains the NIMA binding or PPIase activity. Claims 22-25 and 30-32 recite "WW domain or PPIase domains of Pin1 **fused to "a heterologous polypeptide**" comprising an epitope tag, a carrier protein, a DNA binding domain, a transactivation domain, or an enzyme suitable for use as a label, which read on a WW domain or PPIase domain of SEQ ID NO: 2 is linked to any molecule comprising any polypeptide having such function or characteristics. However, the claims do not limit any particular conserved structural attributes because no metes and bounds can be determined for the terms "comprising", or "consisting essentially of " or "a heterologous polypeptide". The specification merely discloses a Pin1 protein (SEQ ID NO: 2) comprising WW domain, amino acid sequence 5-43, and PPIase domain, amino acid sequence 59-163 of SEQ ID NO: 2. NO other proteins beyond than SEQ IN NO: 2 comprising a WW domain or PPIase domain or meeting the limitation of the claims is ever identified or particularly described.

Instant specification as application publication (20050049404, PGPub) on paragraph [0019] and [0117] teaches that **HA epitope tag** was inserted at the N-terminus of Pin1. Paragraphs [0011] and [0054] of the PGPub teach a nucleic acid construct comprising a **DNA binding domain** operatively associated with the coding sequence of NIMA and member of library comprising **a transactivation domain** operatively associated with a protein encoding sequence. Paragraphs [0085] and [0106] of the PGPub teach **fusing DNA-binding domain** and **transactivation domain** of GAL4 into the library for two-hybrid screen of interaction with NIMA. Paragraph [0051] of the PGPub also teaches that preparation of antibodies for Pin1 polypeptide by immunizing an animal of a peptide conjugated to **a carrier protein** including KLH, BSA etc. However, the specification does not provide any teaching on fusing WW domain or PPIase domain of Pin1 protein with any heterologous polypeptide comprising an epitope tag, a carrier protein, a DNA binding domain, a transacvation domain, or even an enzyme as a label. The specification provides no teaching on specifically fusing the Pin1 protein or any domain of Pin1 protein in the claims with any heterologous polypeptide comprising a carrier protein, a DNA binding domain, or a transacvation domain It is noted that the process of conjugation requires a chemical linking of the full length Pin protein and is not representative of a fusion of the full length Pin protein to a carrier protein, nor is it representative of a fusion between an isolated domain of the Pin1 protein and a carrier protein. Further, it is noted that neither the insertion of the HA epitope tag at the N-terminal of the full length Pin protein, nor the fusion of a DNA binding domain or the transactivation domain of GAL4 with sequences in a library is commensurate in scope to a fusion protein comprising an isolated domain of Pin 1 and a HA epitope tag. Therefore, the specification lacks support for the instant claims drawn to fusion proteins. One of skill in the art, upon reading the originally filed disclosure, would reasonably conclude that applicant was not in possession of the genus of fusion proteins comprising isolated Pin1 domains and heterologous proteins.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any

combination thereof. In this case, the only factor present in the claims of fusing domain of Pin1 with a heterologous polypeptide is fusing polypeptide of Pin1 with HA epitope tag. No identification of any other heterologous polypeptide fused with any domain of the Pin1. Accordingly, in the absence of sufficient recitation of distinguishing structural and functional characteristics of the fusion protein, the specification does not provide adequate written description of the claimed genus. Therefore, the written description is not commensurate in scope with the claims, which read on heterologous polypeptide fused with a domain of Pin1 protein. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the polypeptide of SEQ ID NO: 2 (Pin1), amino acid residue 5-43 (fragment 5-43) and 59-163 of SEQ ID NO: 2 (fragment 59-163), but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

Claims 21, 28, 33-34 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

KAREN A. CANELLA PH.D
PRIMARY EXAMINER